| **PHASE** | **EXTERNAL CONDITIONS IN ORANGE COUNTY** | **SUMMARY & METRICS \*** | **NON-LICENSED RESEARCH STAFF CRITERIA** |
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| **1** | Local COVID-19 hospitalizations rising, testing limited  Public health directives/orders to stay at home (if conflicting orders or directives, follow the most restrictive one) | **Only** [**Critical Research**](https://news.research.uci.edu/defining-critical-research/) **performed in UCI facilities.**   * Interventional treatment trials only * All research that can be done remotely should continue to be done remotely | * Essential only: direct interaction of CRCs with research patients will be limited to the fullest extent possible unless absolutely necessary for conducting critical research. CRCs will not enter patient rooms or other patient care areas unless needed to provide or retrieve documents, supplies, biospecimens or other study related materials – and will follow all guidance about PPE and other precautions while doing so. * All patients are taken through ambulatory screening measures per current UCI Health Policy (maintained on the UCI Health EIP SharePoint site). |
|  | *Preparations for next phase* |  | * *Necessary core facilities are staffed and operational* * *Physical distancing* * *Precautions, including face mask or face covering requirements, cleaning and disinfecting measures understood and in place (See below for OLAC-specific notes)* |
| **2** | Local COVID-19 hospitalizations flatten, then drop  COVID-19 testing capacity increases  PPE shortages still exist  Public health authorities & Governor relax restrictions on ‘essential workers’ (if conflicting orders or requirements, follow the most restrictive one)  Local schools (K – 12) still closed/ teaching remotely for rest of academic year | * Interventional treatment trials * Interventional supportive care, diagnostic, and prevention trials * Time-sensitive assessments of currently enrolled participants in longitudinal observational studies * All research that can be done remotely should continue to be done remotely * Ancillary and correlative trials conducted in conjunction with a routine care/medically necessary visit with study personnel adhering to all required/appropriate safety measures and precautions   ***Plans for sudden return to Phase 1 in place*** | * Essential only: direct interaction of CRCs with research patients will be limited to the fullest extent possible unless absolutely necessary for conducting critical research. CRCs will not enter patient rooms or other patient care areas unless needed to provide or retrieve documents, supplies, biospecimens or other study related materials – and will follow all guidance about PPE and other precautions while doing so. * All patients are taken through ambulatory screening measures per current UCI Health Policy (maintained on the UCI Health EIP SharePoint site). |
|  | *Preparations for next phase* |  | * *Core campus functions are staffed and operational to handle increased load (OLAC, EH&S, CLEB)* * *More core facilities are staffed and operational* * *Labs are able to purchase necessary supplies* * *Physical distancing* * *Precautions, including face mask or face covering requirements, cleaning and disinfecting measures understood and in place (See below for OLAC-specific notes)* |
| **3** | Local COVID-19 hospitalizations continue to decrease  COVID-19 testing capacity near maximum of needed capacity  PPE more widely available  Public health authorities further relax restrictions - standards for return to pre-pandemic conditions (if conflicting orders, follow most restrictive one) | * Interventional treatment trials * Interventional supportive care, diagnostic, and prevention trials * Ancillary and correlative trials that can be conducted in conjunction with a routine care/medically necessary visit and physical distancing can be maintained * Time-sensitive assessments of new and currently enrolled participants in longitudinal observational studies * All research that can be done remotely should continue to be done remotely | * Direct interaction of CRCs with research patients will be limited to maintain social distancing standards and only when necessary for conducting research. CRCs will not enter patient rooms or other patient care areas unless needed to speak with patients and/or clinic staff, provide or retrieve documents, supplies, biospecimens or other study related materials. * All patients are taken through ambulatory screening measures per current UCI Health Policy (maintained on the UCI Health EIP SharePoint site). * Non-essential staff will be allowed access to offices 1-3 days/week to allow for psychological relief and family harmony and return to more normal business operations. Must maintain social distancing and max occupancy per building. |
| **4** | New cases of COVID-19 are low  COVID-19 testing is at maximum needed capacity  PPE readily available and supported by a stable supply chain  Public health authorities further relax restrictions - standards for activity based on ability to physically distance (if conflicting orders, follow most restrictive one)  Childcare options available for parents/guardians | * Interventional treatment trials * Interventional supportive care, diagnostic, and prevention trials * Ancillary and correlative trials that can be conducted in conjunction with a routine care/medically necessary visit and physical distancing can be maintained * Time-sensitive assessments of new and currently enrolled participants in longitudinal observational studies * Cross-sectional or routine observational studies * All research that can be done remotely should continue to be done remotely | * Direct interaction of CRCs with research patients will be limited to maintain physical distancing standards and only when necessary for conducting research. * All patients are taken through ambulatory screening measures per current UCI Health Policy (maintained on the UCI Health EIP SharePoint site). * Non-essential staff will be allowed access to offices 1-3 days/week to allow for psychological relief and family harmony and return to more pre-pandemic-typical business operations. Must maintain physical distancing and any prescribed lower-density max occupancy per building. |
| **End of Stay at Home Order (**if conflicting orders, follow most restrictive one) | Approved vaccine widely available and used in combination with widespread and effective testing, identification and tracing of new COVID-19 cases, with quarantining  No or minimal state or county restrictions | All types of research are allowed | * All business operations fully functioning and stable at post-pandemic “new normal” levels |

* Participants may be accompanied, if essential, by one person for emotional and physical support purposes (study partner) who will also undergo ambulatory screening measures, per policy.

**Clinical Research Categories (adapted from NIH/NCI definitions,** <https://cancercenters.cancer.gov/GrantsFunding/DataGuide#dt4> **)**

**Interventional:** Individuals are assigned prospectively by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic (imaging, laboratory testing, etc.), treatment, behavioral, or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed.

**Ancillary or Correlative:**

**Ancillary:** Studies that are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Only studies that can be linked to individual patient or participant data should be reported.

**Correlative**: Laboratory-based studies using specimens to assess disease risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported.

**Observational:** Studies that focus on disease-affected patients and healthy populations and involve no prospective intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions, but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.